

REMARKS

Regarding the Amendments

Claims 5 and 6 have been amended as set forth in the above complete listing of the claims. These claims have been amended to reflect the new dependency. By the present amendment, cancellation of claims 1 and 3 is requested, without prejudice. Entry of new claims 66-70 is requested. The subject matter of new claims 66-70 is supported by new canceled claims 1 and 3. Accordingly, new claims 66-70 do not add any new matter. Thus, upon entry of the amendments, claims 5-8 and 66-70 will be pending.

As amended, the claims are supported by the specification and the original claims and do not add new matter. The amendments do not require a new search or raise new issues for consideration because they merely address issues already raised by the Examiner or define Applicants' invention more clearly. It is submitted that the amendments place the claims in condition for allowance or in better condition for appeal by reducing the number of issues for consideration on appeal. The amendments were not made earlier in the prosecution because it is maintained that the previously pending claims were allowable. Since the amendments do not add new matter or require a new search or consideration, and place the claims in condition for allowance or in better condition for appeal, entry of the amendment is respectfully requested.

Rejection Under 35 U.S.C. § 112

Applicants respectfully traverse the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for containing subject matter allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time of filing of the Application. Applicants respectfully disagree.

Initially, the Examiner's attention is drawn to the Complete Listing of the Claims, as set forth above. It is noted that claim 1 has been canceled by the present amendment. However, the rejection, as it applies to new claims 66-70 is discussed below.

In particular, it is alleged in the Office Action mailed October 2, 2003 that claim 1 is directed to a modified *Renilla* luciferase having any recognition sites cleavable by any protease. Applicants respectfully disagree. The claims of the invention are not directed to just any modified *Renilla* luciferase having any recognition sites cleavable by any protease, but are particular to a polypeptide with a recognition site at residues 197-200 of SEQ ID NO: 2. The specification sets forth examples, meant to be illustrative and not limiting, which identify a recognition site located at residues 197-200 of SEQ ID NO: 2, where residue 198 is E and residue 200 is D. Such examples are as set forth in new claims 67-70, such as DEVD, VEHD, LETD, LEHD, IEPD, DETD, WEHD, YVAD and VEID. In addition to these structural requirements, the polypeptide of the invention must also have decreased luciferase activity upon cleavage by a protease.

Therefore, the claims of the invention meet the written description requirement of 35 U.S.C. § 112, first paragraph. As rejected claim 1 has been canceled, it is respectfully submitted that the rejection is moot. Accordingly, removal of the rejection is requested.

Applicants respectfully traverse the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for allegedly being non-enabled for luciferases substituted with an unknown recognition site at residues 197-200. Applicants respectfully draw the Examiner's attention to the cancellation of claim 1, however the application of the rejection, as it might apply to new claims 66-70 is discussed below.

The Examiner has noted at page 3 of the Office Action mailed October 2, 2003 that the specification is enabled for "a *Renilla* luciferase substituted with a recognition sites [sic] recited in claim 3 at residues 197-200 of SEQ ID NO: 2". The Examiner's attention is respectfully drawn to new claim 66, which is directed to a purified polypeptide characterized as having *Renilla* luciferase activity and a recognition site specifically cleavable by a protease, where cleavage results in a decrease in luciferase activity and wherein the recognition site is at residues 197-200 of SEQ ID NO: 2, where residue 198 is E and residue 200 is D. Claims 66 -70 set forth

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Filed: July 19, 2000

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exemplary recognition sites, such as from DEVD, VEHD, LETD, LEHD, IEPD, DETD, WEHD, YVAD and VEID.

It is respectfully submitted that the amended claims are not directed to just any recognition site, but sites with specific structural and functional requirements. As such, one of skill in the art would have been able to practice the present invention, as the amended claims specify a polypeptide indicated by the Examiner as enabled. Therefore, the claims meet the enablement requirement of 35 U.S.C. §112, first paragraph. As rejected claim 1 has been canceled, it is respectfully submitted that the rejection is moot. Accordingly, removal of the rejection is requested.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 5-8 and 66-70 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date:

2/2/04



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